Quick Guide

For Clinicians

Based on TIP 28

Naltrexone and Alcoholism Treatment

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Substance Abuse and Mental Health Services Administration
Center for Substance Abuse Treatment
www.samhsa.gov

Contents

Why a Quick Guide? 2

What is a TIP? 3

Introduction 4

Eligibility for Treatment 6

Starting Treatment 9

Ongoing Treatment with Naltrexone 13

Ending Naltrexone Therapy 19

Summation 22

Quick Guide

For Clinicians

Based on TIP 28

Naltrexone and Alcoholism Treatment

This Quick Guide is based almost entirely on information contained in TIP 28, published in 1998 and based on information updated through June 1997. No additional research has been conducted to update this topic since publication of the original TIP.

WHY A QUICK GUIDE?

This Quick Guide was developed to accompany *Naltrexone and Alcoholism Treatment*, Number 28 in the Treatment Improvement Protocol (TIP) Series published by the Center for Substance Abuse Treatment (CSAT), Substance Abuse and Mental Health Services Administration. This Quick Guide is based entirely on TIP 28 and is designed to meet the needs of the busy clinician for concise, easily accessed "how-to" information.

The Guide is divided into six sections (see ***Contents***) to help readers quickly locate relevant material.

For more information on the topics in this Quick Guide, readers are referred to TIP 28.

WHAT IS A TIP?

The TIP series has been in production since 1991. This series provides the substance abuse treatment and related fields with consensus-based, field-reviewed guidelines on topics of substance abuse treatment.

TIP 28, Naltrexone and Alcoholism Treatment

- Addresses the concerns of a broad range of readers including clinicians, counselors, social workers, medical personnel, mental health workers, program administrators, and policymakers
- Lists numerous resources for further information
- Provides a reference on the effects of naltrexone in substance abuse treatment

See the inside back cover for information on how to order TIPs and other related products.

INTRODUCTION

Despite the fact that psychosocial treatment for alcoholics has shown to increase abstinence rates, a significant proportion of clients eventually return to problem drinking. Some of these individuals can now be helped by the drug naltrexone. Naltrexone is an opiate agonist that has been used to treat opioid addiction with the FDA's approval since 1984. When used as an accompaniment to psychosocial therapies for alcohol-dependent or alcohol-abusing patients, naltrexone can reduce

- The percentage of days spent drinking
- The amount of alcohol consumed on each occasion
- Relapse to excessive and destructive drinking

The purpose of TIP 28 and this Quick Guide is to help clinicians and treatment providers better understand naltrexone treatment, its effects, and in what cases it might be helpful for alcoholics.

ATTENTION: Naltrexone can be used as a treatment option for alcoholism but it should not be seen as a replacement for psychosocial interventions. Treatment is significantly more successful when the patient is compliant with both the medication and psychosocial programs.

Naltrexone has been proven to decrease problem drinking—in some cases by almost half—when used with existing treatments, as compared to other, independent, treatment use.

There are many reasons to believe that naltrexone is compatible with a range of psychosocial treatments including 12-Step programs. Self-help groups support the use of nonaddicting medication—it is important to emphasize that naltrexone is not addicting. In studies, participation in community support groups was linked to good outcomes among patients receiving naltrexone. Studies have also shown that naltrexone has been used successfully as an adjunct to day hospital treatment, supportive psychotherapy, and cognitive–behavioral relapse prevention therapy, primary care counseling, and 12-Step facilitation therapy.

Even though naltrexone is an important and valuable tool for alcoholics, treatment providers should tell patients that the medication is not a "magic bullet." Instead, naltrexone is likely to reduce the urge to drink and the risk of a return to heavy drinking.

For more detailed information, see TIP 28, pp. xv–xxi.

ELIGIBILITY FOR TREATMENT

When considering naltrexone therapy, consider

- the patient's eligibility
- dosing strategies
- medical considerations
- ongoing monitoring
- concurrent psychosocial intervention
- the needs of special populations

Suitable Candidates

Naltrexone has been approved by the FDA for use in individuals who have been diagnosed as alcohol dependent, are medically stable, and are not currently (or recently) using opioids. Appropriate candidates should also be willing to be in a relationship with a health care provider or support group to enhance treatment compliance. Studies suggest that patients with high levels of craving, poor cognitive abilities, little education or high levels of physical or emotional stress may derive particular benefit from the addition of naltrexone to their psychosocial therapy.

Naltrexone has few, if any, intrinsic actions besides its opioid-blocking properties: It does not block the physiological or psychological effects of any other class of drug. Watch closely for naltrexone's interaction with other drugs the patient might be taking.

The following are criteria for determining patients' eligibility for naltrexone treatment:

- Individuals with acute hepatitis or liver failure are not suitable candidates.
- Patients requiring narcotic analgesia also are not suitable candidates.
- Patient interest and willingness to take naltrexone are important considerations.
- At the recommended dose of 50 mg daily, hepatic toxicity is very unlikely—continued alcohol use is more likely than naltrexone to cause liver damage.
- Providers should perform a liver function test (LFT) prior to treatment initiation and periodically during treatment—caution should be exercised in using naltrexone with patients whose serum aminotransferases results are five times above normal.

- The final decision to use naltrexone should be based on a risk-benefit analysis—physicians and patients may choose to start naltrexone treatment because the potential benefits of reducing or eliminating alcohol consumption may outweigh the potential risk of naltrexone.

For more detailed information, see TIP 28, pp. xvi–xvii and 5–6.

STARTING TREATMENT

WARNING: Patients should be warned that self-administering high doses of opiates while on naltrexone is dangerous and can lead to death.

Patient Education Comes First

Patients mut be taught how naltrexone works and what to expect while taking it. Treatment providers should not give patients the illusion that it will instantly make their problems go away. Instead, naltrexone is likely to reduce the urge to drink and the risk of returning to heavy drinking. Providers should negotiate a treatment plan with the patient.

Initial Medical Workup

The pretreatment medical workup should include

- A complete physical examination, including the liver
- Various laboratory tests, including LFTs
- A pregnancy test
- A urine toxicology screen
- A complete/updated medical history to rule out possible contraindications

- A substance abuse history that focuses on the use of other substances as well as the patient's history with prescribed medications
- A mental health/psychiatric status screening

Contraindications: Relative and Absolute

A contraindication for taking a prescribed medications is any symptom, circumstance, or condition that renders the medication undesirable or improper, usually because of risk. There are two types of contraindications for naltrexone:

- ***Absolute contraindications*** refer to symptoms, circumstances, or conditions for which naltrexone unconditionally must not be prescribed. These include patients with acute hepatitis, liver failure, chronic opioid dependence or current opioid use, and active opioid withdrawal.
- ***Relative contraindications*** refer to symptoms, circumstances, or conditions with varying degrees of risk that may preclude the administration of naltrexone. These include significant hepatic dysfunction, anticipated need for an opioid to treat an identified medical problem, pregnancy, breast feeding, severe obesity, and use in adolescents.

Some side effects of naltrexone may be less severe than if a person continues drinking. For instance, although initial blood tests after using

naltrexone may indicate some liver dysfunction, reductions in drinking as a result of naltrexone therapy may lead to improved liver functioning.

ALERT: The patient should be abstinent from all alcohol and drug use for 3 to 7 days before initiating naltrexone treatment and it should not be initiated until after signs of acute alcohol withdrawal have subsided.

Management of Common Adverse Effects

Common adverse effects, which may include nausea, headaches, dizziness, fatigue, nervousness, insomnia, vomiting, and anxiety, occur in approximately 10 percent of patients. Some recommendations for dealing with adverse effects are

- ***Patient education:*** If patients are going to experience common adverse effects, these tend to occur early in treatment, and the symptoms generally resolve within 1 to 2 weeks. Support can help patients better tolerate the effects.
- ***Timing of doses:*** Morning doses should be suggested for most patients to establish a routine and ensure better compliance.
- ***Split dosage:*** If there is a need to split the dose, then the patient should take half in the morning and half in the evening, preferably with dinner.

- ***Management of nausea:*** To manage nausea, patients should take naltrexone with complex carbohydrates (such as bagels or toast) and not take the medication on an empty stomach.

For more detailed information, see TIP 28, pp. 7–16.

ONGOING TREATMENT WITH NALTREXONE

- The currently recommended dose for naltrexone is 50 mg/day but this can be decreased to 25 mg/day for patients who do not tolerate the standard maintenance dose but who are qualified for naltrexone.
- It is preferable to decrease the maintenance dose to avoid noncompliance and relapse due to adverse effects rather than ruling out naltrexone as a treatment for patients.
- In cases where patients ask to take naltrexone twice a day to reduce cravings, the same daily dose may be divided in two and given at the times of the day when the craving is strongest.
- Patients who may be considered for a dose over 50 mg/day include those who report persistent feelings of craving, discomfort, and even brief relapse despite compliance with their treatment.
- Before adjusting doses, treatment planners should first consider intensification of other treatment interventions, particularly psychosocial components.
- Naltrexone is not a drug of abuse and providers should view a patient's request for increased

doses as a sign of engagement and motivation in treatment.

Duration of Treatment

The goal for the patient taking naltrexone is to eventually discontinue the medication without relapsing. Providers should individualize the length of naltrexone treatment according to each patient's needs. Initially, the patient can be treated with naltrexone for 3 to 6 months, after which the patient and the therapist can reevaluate the patient's progress. Certain patients may be appropriate candidates for long-term (e.g., to 1 year) naltrexone treatment. Things to consider in extending treatment:

- **Patient interest:** Continued patient interest is usually an indication that the patient is engaged in treatment and perceives the medication as helping maintain sobriety.
- **Recent dose adjustment:** When a clinical response (e.g., abstinence) is achieved only recently, naltrexone can be continued for at least 3 months in order to provide optimal care.
- **Partial treatment response:** Some patients have a partial response to naltrexone. These patients may be appropriate candidates for additional treatment and dose adjustments.

- **Prophylaxis in high-risk situations:** Continued treatment may be considered as prophylaxis for patients who anticipate high risk situations.

Other Clinical Considerations During Treatment

Followup Liver Function Tests

- After initial testing, followup LFTs should be completed after one month of treatment and, if results are acceptable, at 3 and 6 months after the initiation of treatment.
- There should be more frequent monitoring in cases of dose adjustments, high baseline LFTs, a history of hepatic disease, or if disulfiram or other potential hepatic-toxic medications are added to the treatment.
- Physicians should educate patients regarding the signs of hepatic toxicity (white stools, dark urine, yellowing of eyes).
- A clinically significant increase (three times or more) over recent LFT results or an elevation in bilirubin signals a need for discontinuing treatment.

Pregnancy

- During treatment, female patients should be instructed to inform caregivers if they suspect they may be pregnant or experience a delay in their menstrual cycles.

- If a patient becomes pregnant, naltrexone should generally be discontinued.

Naltrexone is an opioid antagonist and will block the effects of a usual dose of therapeutic opioids.

Pain Management

- If the patient has a pain condition that requires treatment, providers should use nonnarcotic methods of analgesia as the first line of treatment.
- If narcotic relief is indicated, patients must discontinue naltrexone use for the period during which analgesics are required.
- In the case of a painful event, such as scheduled surgery or dental work, naltrexone should be discontinued 72 hours prior to the procedure.
- If a patient is taken off naltrexone and put on an opioid analgesic, he or she should be abstinent from the narcotic for 3 to 5 days before resuming naltrexone treatment.
- In emergencies, higher doses of opioid analgesics may be used with extreme caution to override the blockade produced by naltrexone.

- Patients with chronic pain that does not respond to nonnarcotics are not candidates for naltrexone.
- All patients on naltrexone should have a safety identification card in case of an emergency that requires medical attention.

Continued Drinking

- Some patients respond to naltrexone treatment at first by reducing rather than stopping their drinking—total abstinence should be a long-term goal, not a condition of treatment.
- When a patient drinks during treatment, the treatment provider should evaluate whether the patient is taking his or her medication regularly.
- The intensity of care along with expectations placed on the patient may be stepped up.
- Dose adjustments may be indicated.
- Each physician working with a treatment program must participate in the reevaluation of the goals of treatment and those of the patients in order to decide how to proceed.

Use of Naltrexone in Conjunction with Disulfiram

The safety and efficacy of the use of both naltrexone and disulfiram at the same time are unknown and is not ordinarily recommended. Patients should always check with the prescribing physician about any medication taken with naltrexone.

For more detailed information, see TIP 28, pp. 16–21.

ENDING NALTREXONE THERAPY

The Successful Termination of Naltrexone

The usual naltrexone dose of 50 mg/day can be discontinued without tapering. The same appears to be true for higher doses. However, dose reductions may be useful psychologically for some patients. Work with patients in developing a structured plan in the event of threatened or actual relapse. Scheduling follow up visits may be helpful in supporting the patient. Naltrexone may be restarted if the patient and the treating clinicians feel that it may be helpful in preventing relapse.

Monitoring the Outcome of Treatment

The following lists some of the possible criteria that can be used to monitor the outcome of treatment:

- *Compliance with treatment plan:* Patient compliance includes keeping appointments for medication monitoring, prescription refills, counseling sessions, and group meetings as well as keeping agreements about paying for treatment. Naltrexone is highly effective when the patient is highly compliant.
- *Stable abstinence or significant reduction in the frequency and amount of drinking:* Studies suggest that outcomes are better for patients who

are abstinent during treatment. Improvements should be confirmed by patient self reports, collateral reports, and/or biological markers.

- *Markedly diminished craving*: Craving that has diminished greatly is an optimum outcome of naltrexone treatment. To assess craving, the patient's own subjective reports can be largely relied upon.
- *Improvement in quality of life:* Areas that should be assessed include

  Health: Blood pressure, LFT results show improvement, stabilization occurs for other related medical problems that the patient was experiencing when he or she began treatment, signs of increased engagement in health care

  Family: Spending more positive time with children and/or spouse, greater involvement/participation with family members, improved intimate relations, reduced family conflict

  Work/vocational status: Engagement in non-drinking leisure and recreational activities, obtaining employment, improved attendance at work, fewer job related problems

  Legal status: No new parole or probation violations, no new driving under the influence charges

Abstinence from other substances of abuse: The abuse of other substances can be evaluated by random urinalysis, collateral reports, and self reports from patients

For more detailed information, see TIP 28, pp. 22–24.

SUMMATION

It will take an extra effort on the part of both the clinician and the patient to make naltrexone therapy effective. Both parties must be willing to communicate with the other regarding treatment progress and setbacks. However, if both are willing to work at it, naltrexone can have a positive effect by reducing both the craving for and use of alcohol. For patients who are motivated to take the medication, naltrexone is an important tool. In many patients, a short regimen of naltrexone will provide a critical period of sobriety during which the patient can learn to stay sober without it.

Research is still being conducted on naltrexone in an effort to make it even more effective than it already is. This research includes determining optimal dosage regimens, determining the effects of naltrexone in alcohol withdrawal, and the cost effectiveness of naltrexone treatment.

Ordering Information

TIP 28 ***Naltrexone and Alcoholism Treatment***

TIP 28-Related Products

KAP Keys for Clinicians based on TIP 28

Easy Ways to Obtain Free Copies of All TIP Products

1. Call SAMHSA's National Clearinghouse for Alcohol and Drug Information (NCADI) at **800-729-6686**, TDD (hearing impaired) **800-487-4889**
2. Visit CSAT's Website at **www.csat.samhsa.gov**

Other Treatment Improvement Protocols (TIPs) that are relevant to this Quick Guide:

TIP 8, *Intensive Outpatient Treatment for Alcohol and Other Drug Abuse (1994)* **BKD139**

TIP 11, *Simple Screening Instruments for Outreach of Alcohol and Other Drug Abuse and Infectious Diseases (1994)* **BKD143**

TIP 14, *Developing State Outcomes Monitoring Systems for Alcohol and Other Drug Abuse Treatment (1995)* **BKD162**

TIP 20, *Matching Treatment to Patient Needs in Opioid Substitution Therapy (1995)* **BKD168**

TIP 27, *Comprehensive Case Management for Substance Abuse Treatment (1998)* **BKD251**

See the inside back cover for ordering information for all TIPs and related products.

CSAT
SAMHSA

DHHS Publication No. (SMA) 01-3589
Printed 2001